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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,157	12/20/2001	Richard E. Fulton	ARTM 1000-6US	1695

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/027,157

Applicant(s)

FULTON ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### ***Claim Objections***

1. Claims 24, 33, 42 and 51 are objected to because of the following informalities:  
"lease" in line 3 of the claim should be "least". Appropriate correction is required.

### ***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-8, 10-14, 17 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 8, 18-20, 22, 21, 23, 24, 25, 3 and 26 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are written in a broader language than the issued claims.
4. Claims 19-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 27, 29, 31, 39, 43 and 32 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they

are not patentably distinct from each other because the current claims are written in a broader language than the issued claims.

5. Claims 19-27, 28-36 and 46-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 118-122, 124 125, 127-131, 133, 134, 136-140, 142 and 143 of copending Application No. 09/900,801. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are written in a slightly broader language than the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-15, 17-24, 26-33, 35, 36, 46-51, 53 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne et al ('782).

Sirimanne et al discloses a subcutaneous cavity marking device and method, and further discloses taking tissue from the target tissue site; selecting a remotely

visualizable bioabsorbable element; positioning the element at the target tissue site; the element swells from a pre-delivery state to a post-delivery state; the element is harder than the surrounding tissue; a bioabsorbable element; a marker in contact with the filament; at least a portion of the element is radiopaque; the marker element is located at the center of the element; a biopsy is obtained at the target tissue site; the positioning is carried out using remote visualization; testing the tissue sample; if necessary, treating the target tissue; removing additional tissue at the target site if necessary; relocating the target site by finding the element; relocation is done by one of palpation and remote visualization; remote visualization is done by at least one of ultrasound, mammography and MRI; relocation is carried out prior to the treating step; a marker element in contact with the bioabsorbable element; a radiopaque marker located generally centrally within the element; and the radiopaque marker is a permanent marker. See Abstract; Figure 1B; Column 3, lines 29-47; Column 7, lines 55-67; Column 9, lines 6-8; and Column 11, lines 22-36.

Even though Sirimanne et al does not explicitly disclose the element being 1.5 times harder than the surrounding tissue, it is implicitly disclosed since the element can be found by palpation, which would mean the device would have to be harder, to some extent, than the surrounding tissue. Furthermore, the disclosure fails to explicitly disclose the 50-1500% swelling of the device in the post delivery state when compared to the pre-delivery state, but does disclose the device expanding upon delivery from the delivery device. See Figures 5B and 5D.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 16, 25, 34, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al ('782) as applied to claims 19, 28 and 46 above, and further in view of Haaga ('392).

Sirimanne et al, as discussed above, disclose the use of an implantable marker at a biopsy site, but fail to disclose the element is softer in the post-delivery state than in the pre-delivery state; and preventing blood from contacting the element until the element is positioned at the biopsy site, using a hemostatic bioabsorbable element with a non-hemostatic biodegradable outer layer.


Haaga discloses biopsy system with a hemostatic insert and further discloses the element is softer in the post-delivery state than in the pre-delivery state; and preventing blood from contacting the element until the element is positioned at the biopsy site, using a hemostatic bioabsorbable element with a non-hemostatic biodegradable outer layer. See Column 1, lines 11-17; Column 3, lines 16-54; Column 4, lines 3-19 and 25-32; Column 7, lines 20-67; and Column 8, lines 1-9.


Since both Sirimanne et al and Haaga disclose means for marking a biopsy site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Sirimanne et al to include the use of a

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hemostatic insert, as per the teachings of Haaga, since it would provide a means for preventing blood loss at the biopsy site as well as provide a means to relocate the biopsy site at a later time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737, and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

  
BS  
December 9, 2002

  
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